

CLAIMS:

- 1) A composition comprising at least one cationic peptide active agent, at least one neutral structure forming amphiphile, at least one anionic structure forming amphiphile and optionally at least one solvent wherein said composition comprises a non-lamellar phase structure and/or forms a non-lamellar phase structure on exposure to body fluids.
- 2) A composition as claimed in claim 1 wherein said non-lamellar phase is a cubic, hexagonal phase or L_3 phase.
- 3) A composition as claimed in claim 1 or claim 2 wherein said cationic peptide has an isoelectric point of above 7.0.
- 4) A composition as claimed in any of claims 1 to 3 wherein said cationic peptide is a peptide hormone.
- 5) A composition as claimed in any of claims 1 to 4 wherein said cationic peptide is selected from the group consisting of desmopressin, octreotide, salmon calcitonin and human calcitonin.
- 6) A composition as claimed in any of claims 1 to 5 wherein the oral bioavailability is at least 1% when measured as blood plasma concentration of active agent relative to intravenous administration in saline solution.
- 7) A composition as claimed in any of claims 1 to 6 further comprising a peptidase inhibitor.
- 8) A composition as claimed in any of claims 1 to 7 wherein said neutral structure forming amphiphile comprises at least one of glyceryl monooleate, glyceryl monolinoleate, glyceryl dioleate (GDO), dioleoyl phosphatidyl ethanolamine (DOPE), dioleoyl phosphatidylcholine (DOPC) and phytantriol, lyso-oleoyl phosphatidylcholine (LOPC) and mixtures thereof.
- 9) A composition as claimed in any of claims 1 to 8 wherein said anionic structure forming amphiphile comprises at least one fatty acid.

- 10) A composition as claimed in claim 9 wherein said fatty acid is at least one of caproic, caprylic, capric, lauric, myristic, palmitic, phytanic, palmitolic, stearic, oleic, elaidic, linoleic, linolenic, arachidonic, behenic or lignoceric acids, their salts or mixtures thereof.
- 11) A composition as claimed in any of claims 1 to 10 wherein said anionic structure forming amphiphile is present in a quantity sufficient to increase the half-life of said peptide active agent in a solution of carboxypeptidase C by at least 50% relative to the half-life of an equivalent composition not including said anionic structure forming amphiphile.
- 12) A composition as claimed in any of claims 1 to 11 wherein said anionic structure forming amphiphile is present in an amount of 0.5 to 50% by weight relative to the weight of neutral amphiphile.
- 13) A composition as claimed in any of claims 1 to 12 further comprising a fragmentation agent.
- 14) A pharmaceutical formulation comprising a composition as claimed in any of claims 1 to 13 and at least one pharmaceutically tolerable carrier or excipient.
- 15) A composition as claimed in any of claims 1 to 5 which comprises or forms particles of said non-lamellar phase structure.
- 16) A composition as claimed in claim 15 wherein said particles are colloidal.
- 17) A composition as claimed in any of claims 1 to 14 further comprising an oxygen containing biotolerable organic solvent.
- 18) A composition as claimed in claim 17 in the form of a solution which forms a bulk non-lamellar phase upon contact with a body fluid.
- 19) A composition as claimed in claim 18 wherein said composition comprises a diacyl glycerol.
- 20) A composition as claimed in any of claims 17 to 19 wherein said active agent is released over a period of at least 2 to 14 days.

- 21) A method for the formation of a composition as claimed in any of claims 1 to 16 comprising forming particles of non-lamellar phase and/or particles which generate non-lamellar phase on exposure to body fluids, said particles comprising at least one neutral structure forming amphiphile, at least one anionic structure forming amphiphile or salt thereof and optionally at least one solvent, and subsequently contacting said particles with a solution of cationic peptide active agent.
- 22) A method for administering a cationic peptide to a patient comprising injection of a composition as claimed in claim 17 wherein in use said composition subsequently forms a non-lamellar "depot" *in vivo*, upon contact with a body fluid.
- 23) A method for protecting a peptide active agent from enzymic degradation *in vivo* said method comprising formulating said active agent as a composition as claimed in any of claims 1 to 20.